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China Notifies Food Safety Standards Administration Measures to the SPS Committee

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Report Highlights:

On April 2, 2019, China Notified the "Food Safety Standards Administration Measures (draft for comments)" to the WTO SPS Committee as SPS/CHN/1130. The Measures provide guidance and procedures related to the development of local and national food safety standards and the treatment of imported foods without national food safety standards. June 1, 2019 is the deadline for sending comments on the Measures to the SPS Enquiry Point. There is no proposed date of adoption for the Measures. This report provides an unofficial translation of the Measures.

General Information:

BEGIN TRANSLATION

Food Safety Standards Administration Measures (Draft for Comments)

Chapter One General Rules

Article 1 These Administration Measures are formulated to regulate administration of food safety standards pursuant to the Food Safety Law of the People's Republic of China (Food Safety Law) and its Implementing Regulations.

Food safety standards are mandatory standards, which include national food safety standards and local food safety standards.

Article 2 Food safety standards are developed for the purpose of safeguarding public health, and should be based on food safety risk assessment results; the principles for food safety standards should be: science-based, reasonable, safe and reliable.

Article 3 The National Health Commission (NHC) together with relevant agencies under the State Council are responsible for the development of national food safety standards.

Article 4 The procedure for national food safety standard development includes: standard development programming, planning, project initiation, drafting, comments solicitation, review, approval, coding, announcing, tracking and evaluation, and revision.

Article 5 The Evaluation Committee for National Food Safety Standards (the Evaluation Committee) is responsible for reviewing national food safety standards, putting forward suggestions for implementation, and finding solutions on key issues so that the national food safety standards can be implemented.

The Evaluation Committee has a chairperson, deputy chairpersons, a Chief Technical Officer, and technical committees; the Evaluation Committee carries out its duties through chairpersons meetings, technical committee meetings, etc.; the Evaluation Committee has a Secretariat.

Article 6 The Secretariat of the Evaluation Committee (the Secretariat) is located in the National Food Safety Risk Assessment Center (CFSA); it undertakes daily operation of the Evaluation Committee, assists with the planning of national food safety standards, oversees implementation of standards development projects, reviews and reports (to the NHC) draft national food safety standards; the Secretariat also provides publicity, training, guidance, interpretation, tracking, evaluation, research, and communication of national food safety standards, and manages the national food safety standards in the IT system.

Article 7 The health authorities in provinces, autonomous regions, and municipalities (provincial health authorities) are responsible for developing, revising, announcing, and abolishing local food safety standards.

Article 8 It is encouraged to form standards collaboration teams with experts and groups from different areas; the collaboration teams will participate in standards development, tracking/ evaluation, and publicity/training works.

Chapter Two Programing, Planning and Project Initiation of National Food Safety Standards Development

Article 9 NHC works with relevant agencies under the State Council to make schedules for national food safety standards development, and to announce the annual national food safety standards development plans.

The schedule program (program) for national food safety standards development should provide the goals of national food safety standards development, implementation plans, and measures that ensure fulfillment of the goals.

Article 10 Relevant government authorities, research institutes, academies, educational institutions, industry associations, food producers, and traders can submit project initiation proposals for national food safety standards development to the Secretariat.

Article 11 The proposal for project initiation should comply with provisions in Article 26 of the Food Safety Law.

Article 12 Project initiation proposals should contain the food safety problems to be solved, background and reasons for developing the standard, existing food safety risk surveillance and assessment basis, possible economic and social impacts, candidate developers for the standard, etc.

Article 13 The Evaluation Committee should submit its advisory opinions to the NHC regarding national food safety standards development plans.

The Secretariat, pursuant to the project initiation proposal and the Evaluation Committee's advisory opinions, gives suggestions about candidate developers for the standard.

Article 14 NHC, before making decisions about the development program of national food safety standards and the annual national food safety standards development plan, should solicit comments from the public.

Article 15 The projects listed in the national food safety standards development plan can be adjusted in the development process based on actual needs.

If a food safety risk assessment shows potential safety risks from a food (product), or significant problems in food safety risk management are detected, the national food safety standards development or revision projects can be added to the national food safety standards development plan on an emergency basis.

Before developing or revising food safety standards, the Expert Committee within CFSA, for risk management purposes, can suggest temporary limits and temporary testing methods for harmful substances in foods. NHC will work with relevant agencies under the State Council to announce the temporary limits and temporary testing methods for the harmful substances in foods, and notify the (limits and testing methods) to the World Trade Organization.

Chapter Three

Drafting of the National Food Safety Standards

Article 16 NHC signs assignment agreements with the standards developers.

Article 17 Development of national food safety standards should be based on food safety risk assessment results and fully consider the food safety risk assessment of edible agriculture produce; the social and economic development status and the actual needs should also be considered; relevant international standards and international food safety risk assessment results should also be referred to.

Article 18 The standard developer and the person developing the standards, while in the process of developing the standard, should conduct in-depth research and analysis of the issue, fully consult standards users (such as industry associations, food producers, and traders), technical institutes, and experts for their suggestions.

Article 19 The standard developer should complete standard drafting within the given time limit, and submit relevant materials to the Secretariat for review (such materials include the draft standard and the explanations of the developed standard).

The requirements for the submitted material will be formulated by the Secretariat separately.

Article 20 When the standard developer cannot complete the standard drafting without a reasonable cause, or cannot complete the standard drafting according to relevant requirements, NHC will instruct the standard developer to make corrections within given time; if failing to make the correction before the given deadline, the developer will not be assigned a national food safety standard drafting task in the next five years.

Chapter Four Comments Solicitation and Review of National Food Safety Standards

Article 21 The Secretariat conducts preliminary review of the submitted materials for their completeness, format, and consistency with other national food safety standards; based on the preliminary review, the Secretariat will develop the draft standard for soliciting public comment, which will be submitted to NHC in a timely manner.

Article 22 NHC will solicit comments from relevant government agencies and industries, and publish the standard on its website to solicit comments; NHC will follow the notification procedure and notify the draft standards to the WTO.

Should there be significant disagreement about national food safety standards for testing methods, the Secretariat will select a verifying institute to verify the testing method standard.

Article 23 The standard developer should analyze the collected comments and improve the draft standards; for the comments that will not be considered, the standard developer should give explanation of the denial and formulate the draft standard for examination.

Article 24 The Secretariat will invite the technical committee to review the draft standard for examination at an appropriate time.

The technical committee will review the draft standard on its science-basis, practicality and other technical issues.

Article 25 Upon passing the technical committee's review, the standards will be submitted to the chairpersons for review; the chairpersons will draw conclusions about the technical committee's review results and the standard's compliance with relevant laws, regulations, and rules.

Before the chairpersons meeting, the chief technical officer will request heads of relevant technical committees and the deputy chairpersons of the committee to conduct technical review of the standards. When necessary, external experts could be invited to attend the technical review, with participation of the standard developer.

Article 26 For standards that fail to pass the review, the Evaluation Committee should provide reasons and issue the review opinions (to the standard developer). The standard developer should revise the standard according to the review opinions, submit the revised standard to the Secretariat for review, followed by review by the technical committee or by the chairpersons meeting.

If the revision involves change of key contents, the standard should be released for comments by other government agencies and industries, and public comments.

Article 27 Draft standard for examination becomes the draft standard for approval after review by the chairperson meeting. The Secretariat will entrust a professional publishing house to review the draft standard for approval together with the standard developer; the review will ensure accuracy of the standard text. Afterwards, the draft standard for approval will be submitted to NHC in a timely manner.

Chapter Five

Approval, Coding, and Announcement of National Food Safety Standards

Article 28 NHC works with relevant agencies under the State Council to jointly announce the national food safety standards in the form of public notices.

The agencies that approve and publish the national food safety standards, while approving a standard, should examine the development procedure and its compliance with relevant laws, regulations, and rules.

Article 29 Coding of national food safety standards will be performed according to NHC and the Standardization Administration of China's consultation opinions and relevant provisions.

Article 30 There should be a certain period of time between the announcement and the implementation of national food safety standards, which will allow food producers and traders and other stakeholders to prepare for implementation of the standard.

Based on their need, food producers and traders and other stakeholders can implement the standard before the implementation date (within the transition period), and publish the early implementation status.

Article 31 NHC is responsible for interpretation of national food safety standards; the standard interpretation has equal legal power as the text of the national food safety standards.

The Secretariat will organize the standard developers and the developing institutes to provide technical supports for the standards interpretation work.

Article 32 The national food safety standards and their interpretations are published in the NHC website for the public to read and download.

Article 33 Based on necessity, the Secretariat will organize the standard developer to draft questions and answers for key points in standards implementation; passing NHC review, the key points for implementation will be published and used as guidance for standards implementation.

Article 34 If problems emerge in implementing the national food safety standards, county and higher-level health authorities and relevant government agencies should provide guidance and answers to solve

such problems; the standards text, interpretation and frequently asked questions can be referred to as guidance.

Chapter Six Tracking, Evaluation and Revision of National Food Safety Standards

Article 35 After the announcement and implementation of national food safety standards, provincial health authorities should work with relevant government agencies to launch publicities of the national food safety standards and track/evaluate the standards implementation; they will motivate entities within agency and social forces (such as research institutes, education institutions, academies, industry associations, food producers and traders) to collect problems, opinions and suggestions about implementation of the national food safety standards.

Article 36 The problems, opinions and suggestions collected in various regions should be submitted in the "national food safety standards tracking/evaluation and opinion feedback platform" (to the Secretariat) in a timely manner.

Article 37 The Secretariat should analyze the collected opinions collected in standards tracking and evaluation, and provide the analysis to the standard developer. If necessary, the Secretariat could launch *ad hoc* tracking and evaluation projects on key standards.

Article 38 Results of the tracking and evaluation are an important basis for national food safety standards development and revision.

Article 39 After announcing national food safety standards, if the major technical content requires revision, the revision procedure should follow the procedure provided in these Measures for project initiation, draft, comments solicitation, review and approval/announcement.

Article 40 If some individual technical content in a national food safety standard requires correction, adjustment or revision, the revision could be made in form of a standard amendment.

The standard amendment should go through the procedure of comment solicitation and passing the technical committee review, and then apply for signature by the Chief Technical Officer of the Evaluation Committee; after these, it is submitted by the Secretariat to the NHC, and then implemented following the approval and announcement procedure as provided in these Measures.

Article 41 When correcting editorial errors, the Secretariat could instruct the developer to make the changes, and correct the error by announcing the standard correction, which will be submitted to the NHC. The corrected content will be implemented from the date of its announcement.

Chapter Seven Local Food Safety Standards

Article 42 Using risk assessment results as the science basis, the provincial health authorities could organize the development and announcement of local food safety standards; they undertake the publicity, interpretation, tracking and evaluation of the standards, as well as provide guidance/explanations for the standard implementation.

The provincial health authorities are accountable for the safety, science-basis, and practicality of local food safety standards.

Article 43 Local specialty foods refer to foods with traditional consumption in some regions for over 30 years (including foods materials only available in the region, or foods that are produced using traditional techniques), and there is no applicable food safety standard indexes.

Article 44 The local food safety standards include food safety requirements for local specialty foods, testing methods and procedures that match standards for local specialty foods, and the code of hygienic practice for production and operation that match the standards for local specialty foods.

Article 45 Local food safety standards shall not conflict with or repeat provisions in relevant laws, regulations and national food safety standards.

The following foods should not have local food safety standards: foods that have already been covered in the general standards or food standards, infant formula foods, foods for special medical purposes, health foods, food additives, food-related products, new food materials not yet approved, substances listed in the Pharmacopoeia of China (with the exception of substances listed in the catalogue of substances that are both foods and drugs).

Article 46 NHC designates the Secretariat to handle record filing of local food safety standards.

Article 47 The provincial health authorities are encouraged to set up technical collaboration groups to develop local food safety standards.

When two or more provinces are submitting project initiation plans for the same local food safety standard, the Secretariat should consider including the standard in the initiation plan for national food safety standards development.

Article 48 Provincial health authorities should, within 30 working days after announcement of local food safety standards, submit the record filing documents to the Secretariat. The submitted documents should contain the standard text and the standard development explanation (including the electronic documents).

Article 49 The Secretariat regularly analyzes and evaluates local food safety standards; finding the filed local food safety standards violating laws/regulations/national food safety standards, the Secretariat should inform the standard developer of opinions for correction. If the local food safety standard satisfies conditions for national food safety standard, the Secretariat can give suggestions about developing the local food safety standard into a national food safety standard.

Article 50 After announcement and implementation of local food safety standards, if it is necessary to develop national food safety standards, relevant government agencies, research institutes, education institutions, academies, industry associations, food producers and traders could submit project initiation proposals for the national food safety standards.

After the national food safety standards are announced and implemented, the provincial health authority should abolish the local food safety standards in a timely manner; the abolishment should be announced online and notified to the Secretariat.

Chapter Eight Imported Foods without National Food Safety Standards

Article 51 Imported foods currently not covered by national food safety standards (hereinafter referred to as imported foods without national food safety standards) are foods produced outside of China that comply with the producing country/region's standards or international standards, however China has not yet published corresponding national food safety standards for the foods. Imported foods without national food safety standards must comply with the Food Safety Law and the regulations issued by relevant agencies under the State Council. Imported foods without national food safety standards do not include:

- 1. Foods that are covered by existing national food safety standards (the general standards or specific standards for food products);
- 2. Foods that have been announced in government public notices or approved by relevant agencies under the State Council;
- 3. Pre-mixed foods that are mixed with materials that have national food safety standards;
- 4. Products not categorized as imported foods without national food safety standards for other reasons.

Article 52 NHC entrusts the Secretariat to conduct technical examination to identify the applicable standards for imported foods without national food safety standards.

Article 53 Per examination needs, the Secretariat will select experts from the Evaluation Committee for National Food Safety Standards to examine/review the application materials.

If necessary, the Secretariat could invite experts from the National Food Safety Risk Assessment Expert Committee, or relevant government agencies, or technical institutes to participate in the review work.

Article 54 Foreign exporters, foreign producers or their entrusted importers should provide the applicable standards in their country or the international standards to the Secretariat for technical review.

Article 55 NHC, after examining the technical review opinion formed by the Secretariat, will announce the standards that temporarily apply to the product.

Article 56 When there is evidence proving the imported foods without national food safety standards may impose potential risks, or the technical indexes of the applied standard have changed, NHC is responsible to organize (experts to) re-examine the applicable standard for the imported foods without national food safety standards.

Article 57 If it is necessary to develop/revise national food safety standards for the imported foods without national food safety standards, the development/revision should follow provisions in these Measures. When the national food safety standard is announced, the previously applied standard is automatically abolished.

Chapter Nine Supplementary Rules

Article 58 The announced national food safety standards are science and technology outcomes, which are achievements of the main standard developers and can be used to apply for professional titles.

Article 59 Development of standards of pesticide limits and veterinary drug limits in foods and their testing methods/procedures, and the inspection practices of animal and poultry slaughtering, should follow consultation opinions and relevant regulations by the NHC and relevant government agencies (such as the Ministry of Agriculture and Rural Affairs and the State Administration for Market Regulation).

Article 60 These Measures will be implemented on xxx of 2019. The Administrative Measures for National Food Safety Standards released by the former Ministry of Health on October 20, 2010 will be abolished at the same time.

END OF TRANSLATION